40 CFR Parts 720

[OPPTS-50593;FRL-3889-9]

RIN 2070-AC14

Premanufacture Notification; Revisions of Premanufacture Notification Regulations; Proposed Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) mandates that the Environmental Protection Agency (EPA, or the Agency) review the potential health and environmental effects of new chemical substances prior to their manufacture or import and take action to prevent unreasonable risks before they occur. Section 5(a)(1) of TSCA requires that persons notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. Since 1979, EPA has reviewed over 20,000 section 5 notices for new chemical substances. During the intervening years, EPA has implemented a number of non-regulatory initiatives which have enabled the Agency to review a growing number of new chemical substances. In order to achieve further efficiencies and resource savings for both EPA and submitters of section 5 notices, the Agency is proposing a number of regulatory initiatives to reduce the administrative costs/burdens of the section 5 new chemicals program. These proposals would allow EPA to concentrate its limited resources on identifying and controlling those chemical substances most likely to present an unreasonable risk of injury to health and the environment.

DATES: Comments must be received by April 9, 1993. If requested, EPA will conduct public hearings on the proposed rule amendments. Requests to make an oral presentation must be received by April 9, 1993.

ADDRESSES: All comments and requests to speak at the public hearing must be sent to: TSCA Document Control Office (TS-790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-201, 401 M St., SW., Washington, DC 20460, (Phone: 202-260-1532).

Comments should include the docket control number. The docket control number for this amendment is OPPTS-50594. Since some comments may contain confidential business information (CBI), all comments must be sent in triplicate (with additional sanitized copies if CBI is involved). Comments on this proposed rule will be placed in the rulemaking record and will be available in the TSCA Public Docket Office, Rm. NE-G-004 at the above address between 8 a.m. and 12 noon and 1 p.m. and 4 p.m., Monday through Friday, excluding public holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543-B, 401 M St., SW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION:

Electronic Availability: This document, along with three other related documents, OPPTS-50594, 50595, and 50596 is available as an electronic file on *The Federal Bulletin Board* at 9:00 a.m. on the date of publication in the **Federal Register**. By modem dial (202) 512-1387 or call (202) 512-1530 for disks or paper copies. This document and the three related documents are available in Postscript, Wordperfect, and ASCII.

EPA published its final premanufacture notification (PMN) rule (40 CFR part 720) on May 13, 1983 (48 FR 21722) and subsequently amended certain parts of the rule on September 13, 1983 (48 FR 41132) and April 22, 1986 (51 FR 15096).

I Background

A. Authority

Section 5(a)(1) of TSCA requires that persons notify EPA at least 90 days before they manufacture or import a new chemical substance for commercial purposes. For the purposes of TSCA, a new chemical substance is one that is not listed in the Master File of the TSCA Chemical Substance Inventory ("the Inventory"), which consists of substances reported under the Inventory Reporting Regulations (40 CFR part 710) of 1977 and also added via Notices of Commencement of Manufacture or Import (NOC)(40 CFR 720.102) from submitters of premanufacture notices (PMN).

B. History/Rationale

In this document EPA is proposing to amend the Premanufacture Notification (PMN) Rule to reduce the costs of administering the New Chemicals Program and to implement other efficiencies for EPA and submitters. A discussion of the basis for these proposed amendments follows:

1. *Submission of correct chemical identities in section 5 notices and Bona Fide Inventory search notices.* Based on the information reported to EPA, each substance in the Inventory is accurately and uniquely identified by a chemical name that is both systematic and descriptive (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name). For each of the substances whose identities have not been claimed as confidential business information (CBI) by its submitter, a Chemical Abstracts Service Registry Number (CASRN) is also assigned to further identify that substance in the Inventory.

Since the compilation of the Inventory in 1979, EPA has routinely conducted Inventory searches to determine whether each substance newly reported in a PMN or a Bona Fide Notice is already listed. Whenever the Agency can quickly determine that a reported substance is already included in the Inventory, a submitter of a Bona Fide Notice does not have to file a PMN. Similarly, rapid searches of the Inventory may preclude submitters of section 5 notices from waiting for PMN review periods to expire. This may result in considerable time and resource savings for both industry and EPA, and eliminate the expenditure of resources to review or estimate the properties of such substances.

For both PMNs and Bona Fide Notices, a submitter must provide chemical identity information that EPA considers sufficient to accurately describe the substance in question. For PMNs, these requirements are specified at § 720.45(a), and the corresponding requirements for Bona Fide Notices are stipulated at § 720.25(b)(2)(i). An accurate chemical identity is not only necessary for determining whether a substance is included in the Inventory, but also to accurately assess the risk of a new substance and ensure that the substance EPA reviews is precisely the substance the submitter intends to manufacture or import.

Over the past 13 years of the PMN program, EPA has spent a considerable amount of time and resources developing the precise chemical identification data on PMN and Bona Fide Notice substances that are necessary for searching the Inventory and accurately assessing risk. The Agency's resource expenditure on a PMN or Bona Fide Notice is significant even when the chemical identity information is reported correctly. However, at least 25 percent of the submitted notices contain errors, discrepancies, or ambiguities in the reported chemical identity information. The process of identifying and notifying submitters of these problems, requesting and receiving acceptable corrections for the originally submitted information, and keeping track of the delays and suspensions of notice reviews during the correction process multiplies the Agency's initial review burden and utilizes an excessive amount of limited Agency resources.

Therefore, the Agency is proposing to require that submitters of section 5 notices and Bona Fide Notices provide for each reported substance the most currently valid CA Index Name or CA Preferred Name that is consistent with TSCA Inventory listings for similar substances, in order to reduce delays caused by incorrect or ambiguous chemical identities, to expedite Inventory searches, and to save resources. EPA believes this proposed requirement would benefit submitters as well as the Agency.

One of the principal benefits of this proposed amendment to submitters of new chemical notices is that the percentage of cases currently delayed or suspended due to chemical identity problems would be significantly reduced, since submitters would have resolved most of the chemical identity problems, discrepancies, and uncertainties before reporting substances to EPA. A lower percentage of cases being delayed or suspended would not only correspond to a reduction in the number of technical inquiries and requests for additional information from EPA, but also decrease the administrative burdens involving suspended submissions that are currently borne by both the chemical industry and EPA. In addition, significant reductions in chemical identity problems and administrative delays would enable the Agency to issue more rapid responses to Bona Fide Notices.

The currently valid CA names to be required up front from submitters under this proposal would almost always be consistent with TSCA Inventory listings for similar substances, since Chemical Abstracts Service (CAS), the authority on CA nomenclature, assisted EPA in developing chemical nomenclature for the Inventory. The Agency has, to a large extent, adopted CAS' nomenclature conventions. Submitters can consequently benefit from this consistency by being able to know before the start of the Notice review period just how the Agency will identify their substances for TSCA purposes. This knowledge would assist PMN submitters who wish to prepare chemical product literature at an earlier time that identifies the substance to potential customers, and in the case of importers, to the U.S. Customs Service. In addition, this information would help reduce the need to submit PMN corrections or chemical identity amendments.

By establishing correct chemical identities before submitting Notices to EPA, submitters could also more capably conduct their own searches in public sources of Inventory data. As a result, they would be able to determine more often when substances are already included in the Inventory, thus avoiding the submission of unnecessary Notices.

Submitters' early knowledge of correct substance identities would also enhance the chemical industry's compliance efforts with TSCA regulations. A number of submitters in the past have at some point found themselves out of compliance with TSCA by failing to submit PMNs or Inventory correction requests for certain substances they incorrectly thought were on the Inventory. The chance of a submitter inadvertently violating TSCA due to his/her confusion about how EPA would identify a particular substance would be largely reduced if submitters knew firsthand how their substances would most likely be identified for Inventory purposes.

EPA would also derive considerable benefits from this proposal. The Agency would no longer have to devote such extensive resources toward determining correct chemical identities and the most appropriate Inventory descriptions of substances reported in PMNs and in Bona Fide Notices. The current resource

xpenditure, already significant for each otice containing correct chemical formation, is multiplied when the hemical identity information provided y submitters is incorrect, incomplete, r ambiguous.

This proposed amendment would also acilitate and lower the Agency's cost of earching the Inventory for newly eported substances. Since the Inventory as been continually developed based on CA nomenclature, Inventory searches would be easier to perform and more likely to identify matching listings with the use of correct CA nomenclature and CASRNs provided by submitters.

In order to reduce the chance that persons would unknowingly submit incorrect chemical names, this proposal would encourage submitters to obtain correct chemical identity information directly from CAS before reporting substances in PMNs and Bona Fide Notices. However, since the proposal allows submitters to obtain the specified chemical names from any source, persons would not be required to obtain this information from CAS.

2. *Revision of the Bona Fide Notice requirements for requesting Inventory searches.* Manufacturers and importers are responsible for determining whether a substance is a new chemical substance under TSCA and therefore whether they are subject to the section 5(a) notice requirements. The published TSCA Chemical Substance Inventory: 1985 Edition and the 1990 Supplement to the 1985 Edition Of The TSCA Inventory can often be used to determine whether specific chemical substances are already included in the non-confidential portion of the Inventory. Computer tapes containing chemical names listed in the Inventory, which are updated on a semi-annual basis and which the public can purchase from the National Technical Information Service (NTIS), can be used as alternatives to the printed Inventory editions for this purpose. In addition, persons may also choose to conduct searches of the non-confidential portion of the Inventory by accessing the services of any of several commercial or government databases containing Inventory substance information. In 1986, EPA discontinued its service of responding to public requests for routine searches of the non-confidential portion of the Inventory. However, the Agency continues to respond to written inquiries regarding complex chemical identification issues or clarification of Inventory nomenclature or listing policies.

Substances for which the chemical identities are claimed as CBI are listed by TSCA accession numbers and generic chemical names in the publicly available Inventory. Each generic name describes a possible set of similar substances in order to serve as a masked identity for a specific confidential chemical substance. If a chemical substance is listed on the public Inventory under a generic chemical name, it is usually difficult for the public to determine whether a specific substance consistent with that generic name is really a new or existing substance under TSCA. It has always been the Agency's responsibility under the statute to protect from public disclosure any information reported under TSCA that submitters claim as CBI. EPA protects each confidential substance identity by publishing only the generic chemical name chosen or agreed to by its submitter.

To enable a person to know if a given substance matches a confidential chemical substance identity listed in the Inventory, EPA established procedures at § 720.25(b) to inform persons whether a substance they intend to manufacture or import is already included in the Inventory, or whether the substance is considered a new chemical substance subject to the section 5(a) notification requirements. Under these procedures, a person requesting this information from EPA first must demonstrate a bona fide intent to manufacture or import the substance by submitting in writing the information required at § 720.25(b)(2). EPA will not honor any other request to search the confidential portion of the Inventory, since EPA can only disclose the existence of a confidential inventory substance to a third party upon the Agency's receipt of a Bona Fide Notice, as stipulated in the Inventory Reporting Regulations and the PMN Rule, at § 710.7(g)(1) and § 720.25(b)(1), respectively.

Over the past several years, the number of Bona Fide Notices submitted to EPA has steadily increased. Of the Bona Fide Notice substances not found in the Inventory, approximately half have not been subsequently reported in PMNs by the submitters. This phenomenon is unexpected since in the Bona Fide Notice submitters included signed certification statements of their intention to manufacture or import these substances for commercial purposes. Further, there are a growing number of Bona Fide Notices which are found to be incomplete for which submitters fail to subsequently provide complete information, long after EPA notifies them that the minimum information requirements have not been met. These circumstances imply that many Bona Fide Notice submitters may not have a demonstrable intent to manufacture or import these substances.

Although EPA understands that changing business situations can nullify a company's commercial intentions, it is likely that many submitters have reported their bona fide intent prematurely, perhaps before they have sufficiently assessed the technical viability, marketability, or profitability of the substance. The Agency believes that submitters should have reached positive decisions on these and other criteria before genuinely possessing bona fide intentions to commercialize substances. Alternatively, many other submitters may have conditionally intended to commercialize certain substances, depending on whether or not the substances were already included in the Inventory. EPA believes that neither of these circumstances is consistent with a bona fide intent to manufacture or import under TSCA, according to the spirit and intent of § § 710.7(g)(1) and 720.25(b)(1).

In an attempt to promote the submission of Bona Fide Notices that reflect serious commercial intentions, EPA proposes to amend the PMN Rule and the Inventory Reporting Regulations by revising the requirements for Bona Fide Notices, such that the submitted information would more clearly demonstrate a genuine intention to manufacture or import a given substance for a commercial purpose. The Agency believes that the amended provisions of this proposal represent a well-balanced tradeoff from the existing information requirements and will help to ensure the integrity of the Bona Fide Notice program. The amended provisions would not require submitters to generate any new information that they would not already be likely to know at the time they truly have bona fide intentions. The required information concerns basic business and technical questions that any submitter would have already answered in order to make an informed decision to manufacture or import a substance. If one has not already invested the time and effort to seriously think about and answer the types of questions posed by the amended provisions, the Agency believes that it is highly unlikely that this person has established a bona fide intent to manufacture or import the substance. Thus, the revised provisions should not constitute an increased burden to submitters, since persons with a demonstrable bona fide intent should have already answered these questions before a manufacturing or importing decision is reached, and would be able to benefit from or utilize the information developed and obtained in responding to the questions.

EPA believes that these amended revisions would also improve the Agency's ability to protect the CBI of persons submitting notices under TSCA. It has always been the responsibility of EPA to protect from public disclosure any information reported under TSCA that submitters claim as CBI. According to §§ 710.7(g) and 720.25(b), a specific chemical identity listed in the confidential Inventory can only be disclosed to a third party if that person has demonstrated a bona fide intent to manufacture or import the substance for a commercial purpose. Under the present provisions, however, there is the chance that some CBI may be disclosed to Bona Fide Notice submitters that, unknown to EPA, do not have genuine intentions to commercialize substances. Requiring Bona Fide Notice submitters to provide the information requested by the proposed amendments would improve the Agency's ability to protect the CBI of the original submitters of Inventory-listed substances by enabling the EPA to be more selective about which Bona Fide Notice submitters are entitled to receive specific CBI concerning Inventory-listed substances. Consequently, all submitters of PMNs for substances subsequently added to the Inventory or initial Inventory reporting forms could benefit from the resulting enhanced integrity of the Bona Fide Notice program. In addition, EPA would not have to spend significant resources processing notices that do not represent serious commercial intentions.

3. *Amendment of the "Two Percent Rule" for polymers to allow submitters greater flexibility in determining the amount of monomer or other reactant used in the manufacture of a polymer.* The PMN rule requires reporting new polymers on the basis of the amounts of monomers and other reactants used in the reaction, "as charged" to the reaction vessel, and on the dry weight of the polymer manufactured. This approach, which has been in effect since the Inventory reporting regulations were published on December 23, 1977 (42 FR 64572), was adopted because the Agency and the regulated community believed it would be difficult to identify the exact amount of monomers or reactants incorporated in the final polymer. The method of reporting the percent composition of monomers and other reactants "as charged" was viewed as a reasonable approach by chemical and polymer industries.

Due to advanced analytical capabilities developed over the intervening years, certain polymer manufacturers have asked EPA to revise the current "Two Percent Rule" to allow manufacturers the option of determining the amounts of monomers and other reactants that are "in chemically combined form" (incorporated) in a polymer as an alternative to the current practice of requiring reporting based on the amounts added (charged) to the reaction vessel. EPA has considered industry's request and is proposing an amendment to the "Two Percent Rule" to allow this optional reporting procedure. The Agency believes that allowing submitters to report on the basis of amounts incorporated in the polymer could provide a better indicator of physical, chemical, and toxicological properties of polymers. At the same time, this would allow manufacturers greater flexibility in commercial innovation, reduce the number of unnecessary PMNs representing slight variations in polymer composition, and provide greater consistency with international reporting policies. However, as will be described below, the Agency believes there are certain drawbacks and burdens involved in using the method of computation based on incorporated amounts of monomers and reactants.

Under the proposal, manufacturers would still be allowed to use the "amounts charged" method to determine the polymer chemical identity. However, they would also have the option of determining the amounts incorporated in the manufactured polymer. If a company chooses the latter method, EPA believes that it is reasonable to require that such manufacturers maintain in their records analytical data that demonstrate that the amounts of monomers and other reactants incorporated in the manufactured polymer have been accurately determined. This will allow the Agency and the company to verify compliance in a straightforward manner.

EPA recognizes that it was a matter of convenience, rather than one of science, to have thus far required reporting of the amounts of polymer reactants charged rather than the amounts incorporated; the former method requires only "bookkeeping", while the latter may require extensive and expensive analytical work.

After nearly 13 years of experience with the Inventory and PMN reporting rules, however, chemical manufacturers and EPA reviewers have come to realize that the convenience of the "amount charged" approach has drawbacks. In particular, the current approach of identifying many polymers based on monomers and reactants charged to the reactor in quantities significantly larger than the amounts found to be incorporated in the polymer does not properly represent the physical, chemical, and toxicological properties of the polymer.

Under the PMN rule, inefficiently incorporated reactants, reactants charged in large excess, and reactants with other functions besides their reactant ones are often likely to produce reportable polymers, even though the degree of chemical incorporation may be less than or equal to 2 percent. For example, free-radical initiators are often charged in quantities greater than 2 percent in order to start many polymer chains simultaneously and limit the amount of high-molecular-weight polymer produced. Chemical incorporation is inefficient, since many processes other than chain initiation can consume the initiator. The weight of the final polymer that can be attributed to fragments originating from the initiator is often less than two percent by weight. A manufacturer may use many different initiators, all charged at greater than 2 percent, to produce what would be the same polymer if the "incorporated" method of computation was used. The result has been what many manufacturers believe to be excess reporting. Similar problems arise with solvents that have reactive functions, and with neutralizing agents used in excess of their salt-forming capacities. Technical details concerning the "Two Percent Rule" are contained in the paper entitled, "Supporting Document on Computation of Weight Percent of Reactants", which is available in the public docket for this document [OPPTS–50593].

Since the Agency has always believed the actual content of a polymer to be a better indicator of its physical, chemical, and toxicological properties, and settled upon the "amount charged" method of computation as a matter of convenience to industry, it now seems reasonable, in the light of experience, to allow the submitter to optionally use the amounts of monomers and other reactants incorporated, basing the computation on the "imputed charge" as described in the public docket for this document. Therefore, EPA is proposing an amendment to allow optional use of the method to determine percentage composition based on the amounts of reactants present in chemically combined form in the polymer.

The use of the "incorporated" method may have regulatory consequences. The percentage of chemical incorporation of a given reactant, and its "imputed charge" value, could possibly change and result in the need to submit an additional section 5 notice if there was

a modification in the manufacturing process, either inadvertent or intentional, even if there was no change in the amounts and identities of the reactants charged to the reaction vessel. Changes in reaction temperature, in the type of catalyst or solvent used, or in the method and/or order of charging the reactants to the reaction vessel are examples of such processing modifications that could possibly affect the degree of chemical incorporation and the "imputed charge" of a given reactant when the charged amounts of reactants remain unchanged. Such a change could hypothetically cause the weight percentage of a minor reactant to increase from less than or equal to 2 percent to above 2 percent, resulting in the automatic requirement that this reactant be included in the Inventory description of the polymer. If this reactant was not originally intended to be included in the polymer identity for TSCA purposes, the processing change could result in the isolation of a different, reportable polymer substance before a section 5 notice was submitted. Consequently, persons could find themselves in violation of the PMN Rule, even though the charged amounts of the reactants had never been changed. Compared to using the "as charged" method, it would be more difficult to prevent this type of potential TSCA violation when the computation method based on incorporation is used. Thus, the potential regulatory liability to industry could increase to the extent that the "incorporated" method is used.

The proposed amendments make clear that an Inventory correction request or a PMN correction request received after the end of the notice review period will not be allowed to cover a new polymer identity that may occur if a processing change causes the "imputed charge" value of a reactant to increase from less than or equal to 2 percent to above 2 percent, when reported percent composition data are based on amounts incorporated. In addition, an Inventory correction request or a PMN correction request received by EPA after the end of the notice review period will not be allowed to cover a change in the TSCA chemical identity of a polymer that may occur if a submitter changes computation methods from the "incorporated" method to the "charged" method, or vice versa. A chemical identity correction request of this type will only be accepted if this request is received by EPA during the applicable section 5 notice review period.

4. *Submission of multiple photocopies of section 5 notices.* EPA, in order to complete its review of each section 5 notice within statutory timeframes, must currently make multiple copies of the PMN form and any accompanying documents to make them available to many technical reviewers in the Agency simultaneously. Making these copies presents difficulties in terms of time and expense to the Agency. For example, some documents received are in non-standard sizes, or have other characteristics that make photocopying difficult. Further, duplication of documents containing CBI requires special handling procedures. These problems lead to inevitable time delays for staff access to documents. Therefore, the Agency is proposing an amendment to require that, in addition to the original copy of the section 5 notice and attachment(s), plus one sanitized copy in which CBI has been deleted, submitters provide EPA with two additional copies of the notice itself that include all continuation sheets for information required in the notice and two additional copies of test data, other data, and any optional information provided as attachments to the notice. EPA believes that this proposal will expedite the PMN review process by allowing reviewers to have access to the documents in a more timely manner and enabling the Agency to shift resources from photocopying services to scientific reviews.

5. *Electronic transmission of section 5 notices.* EPA is proposing to amend § 720.40 to allow reporting via magnetic or other electronic media. Because the Agency is still in the early stages of planning for reception of electronic submissions, it is premature to specify a format. However, the Agency is developing standardized electronic reporting formats and mechanisms such as submission by magnetic tapes, diskettes, and electronic forms. EPA believes that transmission of submissions via electronic media may be quicker than mail, if Electronic Data Interchange (EDI) is adopted as a transmission mechanism. In any case, direct loading of data to a computer system is more efficient than keystroke data entry and ensures data quality. Readers are referred to the Federal Register of July 30, 1990 (55 FR 31030) for further discussion of the Agency's policy on electronic reporting.

6. *Standard form for Notices of Commencement (NOC).* Manufacturers and importers are required at § 720.102(b) to submit a NOC to EPA's Document Control Officer within 30 calendar days of the first day of manufacture or import for a commercial purpose. The NOC must be submitted by the PMN submitter. Currently, there is no required reporting form for a NOC. Although EPA provides a voluntary one-page NOC form to submitters with PMN receipt acknowledgement letters, submitters may use any type of letter or form that includes the necessary information. Many submitters routinely use the NOC form, and its use has simplified EPA's receipt of NOC information. In cases where the voluntary NOC form is not used, a significant number of NOCs has created difficulty because they were not recognized as NOCs or contained confusing, missing, or unnecessary information. These problems have resulted in a waste of time and resources for both submitters and EPA personnel who must prepare or review these notices.

EPA is proposing the mandatory use of a one-page NOC form, which the Agency believes would enable all NOC submitters to benefit from the simple, quick NOC process that users of the voluntary form already possess. The required use of such a form would also reduce EPA processing time for NOCs.

C. Other Initiatives Being Considered

The Agency is also considering the following initiatives but is not proposing any additional PMN rule amendments at this time.

1. *Development of requirements that all reporting facilities provide certain information about their geographic location.* To date, for PMN reporting purposes, the Agency has requested the street address of manufacturing, processing, and use facilities under the control of the submitter. The Agency is currently considering developing requirements for an EPA-wide policy which would require that all facilities reporting under any EPA-administered program provide certain information about their geographic location beyond the general street address. This information would assist environmental analyses and allow data to be integrated based on specific locational information. In addition, this approach would promote enhanced use of EPA's extensive resources for cross-media environmental analysis and management decisions. The policy is expected to include: latitude/longitude coordinates, specific method used, a text description of location, and an estimate of accuracy. In order to incorporate this policy into the PMN rule, the Agency has established a workgroup to analyze and propose requirements for this type of specific information in section 5 notices in order to better describe the sites of manufacture and processing of a new chemical substance. The Agency is requesting comments on whether this

information should be included in all section 5 notices and NOCs.

At some future date, the reporting forms for all section 5 submissions may be revised to provide space for the entry of latitude/longitude coordinates for each site of manufacture, importation, or processing under the submitter's control, an indication of the specific method used to determine coordinates, a text description, and an estimate of accuracy. Many companies already report this data under other EPA rules, so providing this data would not be unduly burdensome. Also, it need only be determined once per facility, as the latitude/longitude coordinates presumably wouldn't change. Possible issues include the definition of "facility", as the site of research and development activity may be different than that of manufacture or importation. The possible need to submit additional and/or updated locational data with the NOC is also being studied.

2. *Enhanced review of all confidential claims submitted to the Agency.* The Agency is not proposing to amend the language of the rule pertaining to CBI. However, EPA is giving notice that it intends to review each PMN submission containing a CBI claim and make appropriate determinations on the validity of that claim. This higher level of scrutiny arises from EPA's conclusion that claims for CBI protections are being used indiscriminately without regard to statutory or regulatory restrictions. Because of this, and the need to handle all claimed material as CBI until such claims are verified, withdrawn, or rejected, CBI procedures consume an inordinately large amount of Agency resources that may not be justified.

EPA requests that PMN submitters carefully review and tailor each CBI claim so that only that information which must be confidential is claimed CBI. Submitters should review the statutory CBI provisions contained in TSCA section 14, the general CBI regulatory provisions contained in 40 CFR chapter I, § 2.201, et seq. and the specific PMN CBI regulatory provisions contained in 40 CFR 720.80, et seq. before making any confidentiality claims.

Furthermore, if a submitter chooses to submit a CBI claim in a PMN (or other section 5 notice), the submitter must provide a copy of the submission (including all health and safety data) for the public file with all confidential data deleted as required at § 720.80(b)(2). The failure to comply with this requirement may result in the PMN being declared incomplete in accordance with § 720.65. If the submission is declared incomplete the notice review period for the PMN substance will not begin until the matter is rectified.

The confidentiality provisions of the Rule take into consideration the various requirements of the Act, including the need: (1) To provide nonconfidential material to the public, (2) to give EPA information it needs to respond to Freedom of Information Act (FOIA) requests, (3) to allow persons to assert claims of confidentiality, and (4) to reduce uncertainty about the criteria EPA will use in making confidentiality determinations.

The regulated community is reminded that confidentiality claims asserted in the PMN, including those for chemical identity, will be reviewed in accordance with the procedures set forth in 40 CFR part 2, subpart B.

Concerning chemical identity information included in health and safety studies provided in the PMN, the Agency considers the specific chemical identity always to be part of a health and safety study even when it does not appear in the study. As such, under TSCA section 14(b), EPA may not withhold from the public the data from health and safety studies, including specific chemical identity. The only exception to this policy is if disclosure would reveal confidential processes used in the manufacturing or processing of a chemical substance or mixture, or reveal the proportions of a mixture, or if the specific chemical identity is wholly unnecessary to interpret the health and safety studies. This issue was previously discussed in the final PMN rule of May 13, 1983 (48 FR 21739–21740). Specific language regarding EPA's authority to deny certain claims for confidentiality in a health and safety study appears at 40 CFR 720.90.

Lastly, with regard to CBI claims filed in a NOC, submitters are reminded that under no circumstances may they assert a CBI claim for chemical identity in an NOC if the submitted chemical identity was not claimed CBI in the PMN.

CBI claims asserted for chemical identities submitted in PMNs are not automatically renewed upon Notice of Commencement. EPA, consistent with the NOC regulations at §§ 720.102 and 720.85(b), requires CBI assertions for the chemical identity of a substance to be fully substantiated upon Notice of Commencement. Despite the existence of a CBI claim for chemical identity in the NOC, the chemical identity will be placed on the public inventory without further notice from EPA if not accompanied by appropriate substantiation of this CBI claim.

II. Discussion of Proposed Amendments

1. *Correct chemical identity.* EPA is proposing to amend § 720.45(a) of the PMN rule to require that submitters of section 5 notices and Bona Fide Notices provide the most currently valid Chemical Abstracts (CA) Index Name or CA Preferred Name for each reported substance that is consistent with TSCA Inventory listings for similar substances. This proposal will require that a currently valid Chemical Abstracts Service Registry Number (CASRN) consistent with this CA Name also be reported for the substance if it already exists for that substance. Under the current PMN Rule, CA nomenclature is indicated as a preferred, but not a required, chemical naming system for PMN reporting. Therefore, submitters can presently identify the PMN substance using alternative nomenclature. The proposal would retain all of the other chemical identity information required at § 720.45(a), including molecular formula and chemical structure information. However, for substances not able to be characterized by a single chemical structure, the submitted structural diagram must be as complete as one can reasonably ascertain. Failure to fully comply with the chemical identification elements of this requirement would result in the notice being declared incomplete by EPA pursuant to § 720.65(c)(1). Such incomplete notices will not be processed or reviewed by the Agency until the chemical identification requirement is satisfied.

Although a CAS Registry Number (CASRN) is not routinely required for a reported substance if a CASRN is not already available, and though the proposal only requires that CASRNs be reported for substances that already have them, EPA strongly recommends that submitters provide CASRNs for all reported substances, especially when the chemical identity is not being claimed as CBI. Having more substances reported with CASRNs would save EPA resources involved with chemical review and inventory searching. Submitters would provide a CA Index Name or CA Preferred Name that is consistent with the application of the 9th Collective Index (9CI) of CA nomenclature rules and conventions. Whether to report a CA Index Name or Preferred name for a substance depends on how well-defined the chemical identity of the substance is with respect to the existence of a definite molecular formula to describe it; any given substance can only be properly assigned either a CA Index Name or a CA Preferred Name, according to CA

nomenclature policies. A CA Index name is assigned to any substance having a known molecular formula, whereas a CA Preferred Name is given to any substance having no definite molecular formula.

For well-defined substances appropriately named using CA Index nomenclature, the specific chemical name chosen as most accurately describing the substance should be based on all that the submitter can reasonably ascertain about its chemical structure, including, where applicable, the degree of structural specificity of the substance (i.e., whether or not specific isomers are intended to be produced in a reaction). For poorly defined substances properly named using CA Preferred nomenclature, the specific name of choice should be based on the submitter's knowledge of the identities of the chemical precursors used, the sources of the reactants (i.e., synthetic, isolated or obtained by processing from certain naturally occurring materials, etc.), the nature of the reaction, and the types of chemical substances constituting the product combination, etc.

For any type of substance reported, one needs to consider whether there are any impurities or byproducts of no commercial value existing in the product composition in order to know which product components are reportable. Impurities or byproducts of no commercial value are not considered reportable substances under TSCA.

When more than one substance results from a reaction, one should determine whether or not the product combination can be viewed for TSCA purposes as a mixture of separately reportable substances. For example, when the intended product combination is known to always be completely composed of a specific number of identified substances that do not react with one another, the combination can be represented as a mixture under TSCA. If this is not the case, then a single chemical name must be used to collectively describe the product combination as one substance.

Concerning the degree of chemical structure information that can be reasonably ascertained for a given substance, submitters should understand that, for TSCA Inventory purposes, all substances are categorized by EPA into two groups according to the degree of certainty about the chemical structure of a substance: Class 1 and Class 2. Class 1 substances are those of precisely known chemical composition for which a single, complete structural diagram can be drawn. Class 2 substances are those having chemical compositions not completely definite or known and, therefore, they cannot be characterized by definite, complete chemical structure diagrams. This proposal would require complete structural diagrams to be provided for Class 1 substances; Class 2 substances would require partial structure diagrams that are as complete as can be ascertained from the Class 2 chemical identity.

This proposed chemical identification requirement could be satisfied if the submitter uses the services of CAS, or the services of another chemical information organization, service bureau, or consultant that the submitter considers capable of generating correct CA names, chemical structure diagrams or molecular formulae where appropriate, and obtaining necessary CASRNs. Alternatively, the submitter could search publicly available databases to retrieve this information, if available, or attempt to generate a name without assistance from another person or organization, if the submitter has sufficient knowledge about CA 9CI nomenclature rules and conventions and about how similar substances should be named for the Inventory. Information describing CA nomenclature rules and conventions can be obtained from CAS. Printed copies of the non-confidential Inventory can be purchased from the Government Printing Office, and computer tapes containing this Inventory information can be purchased from the National Technical Information Service (NTIS).

Regardless of who or which mechanism the submitter uses to determine correct chemical identifications, in order to obtain the currently correct chemical names for substances before reporting them to EPA in section 5 notices or Bona Fide Notices, submitters would be expected to provide the party generating the CA nomenclature with the same chemical identity information that the submitter would have to send to EPA if reporting the substance in a PMN: the same types of information, levels of detail, and degrees of specificity, etc. The party assigning a chemical identity for the purpose of a substance being reported in a PMN or Bona Fide Notice should ensure that the name choice reflects the current CA nomenclature rules and conventions, as well as how similar substances are named for the Inventory, or else the chemical name will be incorrect and the notice could be declared incomplete by the Agency.

In order to meet the proposed requirement, submitters could choose between two optional methods of obtaining the chemical identification of any substance to be reported. These alternatives are described below as Method 1 and Method 2. Submitters would need to indicate in each notice which of the two methods is being used.

Method 1. A submitter using this method would obtain the correct chemical identification directly from CAS prior to submitting a notice to EPA. EPA understands that CAS would set up and operate a special extension of CAS Registry Services for identifying substances to be submitted under TSCA. CAS would provide such services pursuant to arrangements between CAS and persons informing CAS that their substances will be reported to EPA in a PMN, an exemption application, or in a Bona Fide Notice.

Submitters would call or write CAS directly for complete instructions on how to use the special extension of CAS Registry Services for TSCA submitters.

Submitters would be required to provide a copy of the chemical identification report obtained from CAS along with the completed PMN, to verify that they obtained the information directly from CAS.

EPA believes that most submitters would find it advantageous to utilize the services of CAS to meet this requirement. CAS is generally recognized as a world authority on substance identity, and is the ultimate source of the most current and correct CA nomenclature and CAS Registry Numbers. Furthermore, only CAS can generate new CAS Registry Numbers. CAS also developed the nomenclature conventions that are widely used by other organizations throughout the world, and has, since 1977, assisted EPA in the development of the TSCA Inventory and the identification of the Inventory's substances. Many submitters of section 5 notices have been voluntarily obtaining chemical identities from CAS on a routine basis before reporting substances to EPA, thereby benefitting from the early recognition and resolution of chemical identity uncertainties. Furthermore, due to CAS' familiarity with TSCA Inventory and nomenclature policies, EPA believes that chemical names and other chemical identity information assigned by CAS according to this method would almost always be acceptable to the Agency. For these reasons, EPA would strongly recommend that submitters use the services of CAS to satisfy the amended provisions.

Submitters should note, however, that if EPA disagrees with the identification assigned by CAS to a given substance, the Agency reserves the right to be the final authority on how a reported

substance should be named and represented for the Inventory. In the rare event EPA does not agree with a chemical name, CASRN, chemical structure or molecular formula provided to a submitter by CAS for TSCA purposes according to Method 1, EPA would work with CAS under an existing technical support contract to either modify the submitted chemical identity when necessary or confirm that the CAS' identification is most appropriate, to ensure that a correct TSCA description is assigned. Using Method 1, there would be no delay or additional cost to the submitter resulting from an identification error by CAS or an identity verification request by EPA, and the review period would continue uninterrupted. EPA would assume responsibility for resolving chemical identity problems occurring when Method 1 is used.

Method 2. Using this method a submitter may obtain the required chemical identity information from any chemical information organization, service bureau, or consultant, from someone on the submitter's staff, or can retrieve or develop the proper CA identifications himself/herself. EPA emphasizes that with this method submitters would need to provide for each substance a correct CA Index or Preferred Name and other chemical identity information, as stipulated under § 720.45(a), that are consistent with Inventory listings for similar substances. It would be the submitter's responsibility under Method 2 to seek the required information from a source the submitter believes to be sufficiently knowledgeable about CA nomenclature conventions and TSCA Inventory listings.

In contrast to Method 1, if a submitter uses Method 2 and reports any chemical identity information that is considered incorrect by EPA, the submitter, not the Agency, would be considered responsible for correcting the chemical identification. EPA would declare such a notice incomplete under § 720.65(c)(1) and would not further process or review it until the submitter provides the fully correct chemical identity information stipulated under the proposed amendment.

Concerning the task of generating correct CA nomenclature, it should be noted that there are many chemical names on the CAS Registry File, particularly CA Preferred Names used for indefinitely described substances, that are not appropriate for uniquely identifying substances on the Inventory. Thus, the application of just the CA nomenclature rules to name a new substance would not guarantee an acceptable chemical name for TSCA purposes. One must also be familiar with the ways in which similar substances are listed in the Inventory.

Regardless which method is chosen by a submitter for properly identifying a reported substance, EPA remains the final authority in naming new substances under TSCA.

In order for submitters to have ample time to become familiar with the process of obtaining chemical identity information from CAS, another chemical information service, or a consulting party for obtaining chemical identifications, it is recommended that submitters contact their chosen source at least 1 or 2 months before the intended submission date of a notice. This is especially important the first time one would have to report under this proposed amendment.

EPA would also caution submitters, however, not to obtain or develop a chemical identification more than several months ahead of when they intend to submit a notice for the substance to the Agency. Due to occasional changes or modifications in CA nomenclature rules and conventions, a CA name that was not recently obtained or developed could represent obsolete CA nomenclature and, therefore, be incorrect or inappropriate for Inventory listing purposes by the time a notice is submitted. The Agency occasionally updates its Inventory listings for existing substances having identities that are affected by revised CA names and changes or modifications in CA nomenclature rules and conventions.

EPA anticipates that many submitters would consider chemical identity information and/or submitter identity information given to CAS (by Method 1) or another third party (by Method 2) to be confidential or trade secret information. It is the position of EPA that no information can qualify as TSCA-CBI until it is received by EPA in a notice reported under a provision of TSCA. Therefore, provisions for handling any confidential information first submitted to CAS or another outside party must be arranged directly with that party. Submitters should not assume that CAS or another outside party is required to adhere to EPA-regulated TSCA-CBI procedures regarding the possession, handling, labelling, storage, tracking, auditing, or other processing of this information.

However, based on currently available information, it is EPA's understanding that any confidential, proprietary, or trade secret information that CAS would receive by Method 1 of this proposal prior to it being reported to EPA would be handled in accordance with the long-established security procedures and policies that CAS has implemented to safeguard any confidential information provided by its customers. A considerable number of large corporations and government agencies appear to have entrusted their confidential substance information to CAS for database building and ongoing search/retrieval projects. There have also been many customers of CAS Registry Services, including submitters of section 5 notices, who have submitted their confidential substance descriptions for assignment of CA names or retrieval of existing CASRNs. Thus, it appears that CAS has had considerable experience in meeting the expectations of outside organizations for protecting their confidential information.

When submitting a chemical to CAS or any other information service, a submitter who indicates that the substance identity is confidential information should be aware that a CASRN for that substance may already exist due to CAS' prior knowledge from another source of the existence of that substance. In such a case, the chemical identity will already have been assigned a CASRN and placed by CAS in its publicly accessible files. Based on its knowledge of CAS' procedures, EPA believes that CAS currently does not place the substance identity into the publicly available CAS Registry File, if not already present there, when a submitter has requested confidential treatment of the information. However, EPA cannot ensure that CAS will continue this practice in the future, nor can EPA ensure how other services handle this type of information. As always, it is ultimately the submitter's responsibility to ensure that the information service it chooses to employ properly protects the confidentiality of its data, and does not utilize this information for its own gain against the wishes of the submitter.

Submitters choosing to use Method 2 should inquire how any other information service, consultant or party receiving their confidential information will handle, protect, and use such information.

Submitters sometimes do not possess complete chemical identity information about a substance they intend to import because of the proprietary chemical identity claims of certain foreign chemical exporters. In such situations, when the foreign exporter will not disclose confidential chemical identity information to the importer who submits a section 5 notice or Bona Fide Notice, submitters would be expected to

request that the foreign exporting party follow the procedures specified by either Method 1 or Method 2. The chemical identity information could then be provided directly to EPA by the foreign supplier as a joint submission or as a letter of support which references the importer's notice and PMN User Fee TS Identification Number, according to 40 CFR part 700.

Some submitters of section 5 notices or Bona Fide Notices only know part of the chemical identity of their substances, because they contain or are manufactured from purchased substances having specific chemical identities that may be claimed confidential by the supplier. In such cases, the submitter typically identifies the substance only by tradename, generic chemical name, or in terms of partial composition information listed in a Material Safety Data Sheet (MSDS) or in other product literature.

In this situation, due to the complexity and logistical obstacles to generating correct CA nomenclature and other chemical identity information for a substance based on multiple submissions from different sources, EPA is not asking either the submitter or the chemical supplier to first develop or obtain a correct CA chemical identification of the given substance. Rather, the notice submitter would first report whatever is known about the substance identity to EPA in the section 5 notice or Bona Fide Notice, and would arrange for the supplier of the proprietary substance to send a letter of support containing the specific chemical identity of the supplied chemical directly to EPA, referencing the submitter's notice and User Fee TS Identification Number, if appropriate. The letter of support must contain the same PMN User Fee TS identification number used in the notice, so that EPA can be sure of properly linking the two submissions. EPA would not start the statutory review period until it receives all parts of a joint notice, or all necessary supporting documents providing chemical identity information for a notice.

2. *Revised requirements for Bona Fide Notices.* The Agency is proposing to amend § 720.25 to revise certain provisions of the procedures to establish a bona fide intent. The proposal would reduce or simplify existing analytical information requirements, modify or clarify other existing information requirements, and request three other types of information in notices. This section, with its amendments, would supersede the corresponding section of the Inventory Reporting Regulations [§ 710.7(g)].

Concerning the information currently required at § 720.25(b)(2) to establish a bona fide intent, the proposal would eliminate the need for elemental analysis data [§ 720.25(b)(2)(iv)] while reducing and simplifying the other analytical information requirements [§ 720.25(b)(2)(v)]. Two other parts of this section, regarding chemical identity information, and the description of research and development (R&D) activities and use [§ 720.25(b)(2)(i) and (iii), respectively] would be modified and/or clarified. There are three new information requirements that ask about the most probable manufacturing site and process to be used, as well as an approximate date when the submitter would be likely to submit a section 5 notice for the substance if it is not found in the Inventory. EPA believes that the proposal represents a balanced trade-off of requirements between the existing and amended provisions, which will enable persons to better demonstrate a bona fide intent while the Agency is better able to protect the CBI of the original submitters of Inventory substances. The additional information or data requested in the proposed amendment is easily ascertainable by the submitter, and would likely have been already determined by the time the submitter has a bona fide intent to manufacture or import a substance for a commercial purpose. Persons who have not obtained the information or made decisions about the substance requested by the proposed requirements would not appear to be at the proper commercial product development stage to have a true bona fide intent concerning this substance. According to § 720.25(b)(2)(i) of the proposed amendments, submitters of a Bona Fide Notice must provide, as stipulated in the amended provisions of § 720.45(a), a currently correct CA Index Name or CA Preferred Name, whichever is appropriate, a currently correct CASRN if the substance already has a CASRN assigned to it, plus a molecular formula and a complete or partial chemical structure diagram if they are known or reasonably ascertainable, as stated earlier in this Unit of the preamble. Having the currently correct CA identification for a substance is important to EPA, because the reporting of incorrect, inconsistent, ambiguous, or obsolete chemical names, molecular formulae or chemical structure information, or names that are not CA Index or CA Preferred Names, causes extra resources to be spent by EPA establishing the best descriptions for substances under TSCA, searching the Inventory, and performing risk assessments. Failure to fully comply with the chemical identification elements of this requirement would result in the notice being declared incomplete by EPA.

The proposed amendment would modify the current requirement for a description of R&D activities conducted to date on the substance and the purpose for manufacturing or importing it [§ 720.25(b)(2)(iii)]. Since two different types of information are requested in this section and many submitters have in the past inadvertently omitted one of them in their notices, EPA proposes to make the requirements clearer by separating its requests for descriptions of R&D activities and purpose for which the submitter will manufacture or import the substance into different parts of the amended rule text [§ § 720.25(b)(2)(iii) and 720.25(b)(2)(iv), respectively]. In § 720.25(b)(2)(iii)(A), EPA elaborates on its information request by listing some of the general types of R&D activities that should be reported. In addition, the year in which R&D was started by the submitter on the substance is also requested. EPA believes that these modifications will serve to better enable the submitter to indicate the scope and length of its commitment towards developing the substance for commercial use. EPA would prefer that this information be briefly stated in a few sentences.

In § 720.25(b)(2)(iii)(B), EPA would provide an alternative reporting requirement for importers who do not perform R&D activities on the substance and have no knowledge of R&D activities that may have been conducted outside of the United States. Such importers would be allowed, in lieu of presenting research or development information, to indicate for how long, and in which country, a given substance has been in commerce outside of the United States, as well as to state whether they believe that the substance has already been used outside of the United States for the same commercial application(s) intended by the submitter. This alternative requirement would be similar to the current, informal EPA practice allowing such a prospective importer to satisfy § 720.25(b)(2)(iii) by providing certain information on foreign commercial activity of the substance.

In 40 CFR 720.25(b)(2)(iv), for clarity, the term "purpose" has been replaced by the phrase "major intended application or use" because some submitters have misunderstood the type of information being requested and have not provided a description of the intended end use.

EPA is proposing to simplify the analytical data requirements at § 720.25(b)(2)(v) to reflect the current practice of most submitters to provide an infrared spectrum to characterize the chemical substance. The proposal will require an infrared spectrum, unless infrared analysis is not suitable for the substance or does not yield good structural information for the substance. As an alternative in such cases, the proposal requires one to submit a spectrum or instrumental readout from another method of spectral or instrumental analysis that yields better structural or compositional information.

Section 720.25(b)(2)(vi) of the proposed amendment consists of a minor but new information requirement to estimate the month and year in which the person would intend to submit a section 5 notice for the substance if it is not found in the Inventory. EPA believes that a Bona Fide Notice submitter would have already thought about a future timeframe for reporting the substance under section 5 if it is a new chemical substance. The intent of this requirement is not to legally bind the submitter to a certain date for submission of a PMN. However, the information would be one of many factors which will help EPA to determine whether the person has demonstrated a bona fide intent. Also, if EPA could anticipate how many Bona Fide Notice submitters may report their substances in PMNs in a given year, the Agency may be able to better allocate resources for reviewing them.

Section 720.25(b)(2)(vii) of the proposal is a new requirement requesting the address of any one site under the submitter's control where the substance is anticipated to most likely be manufactured or processed in the future for a commercial purpose.

Section 720.25(b)(2)(viii) of the proposal is a new requirement by which a manufacturer must briefly describe the most probable manufacturing process that the submitter would use to produce commercial quantities of the substance. Importers would have the alternative of briefly describing how the substance would most likely be processed or used at a site controlled by the submitter, or if no processing or use of the substance is anticipated to occur at a submitter-controlled facility, a submitter could just state that such commercial activity is not expected to occur. This information is not intended to be legally binding, but rather to assist EPA in determining whether the submitter appears to have serious intentions for commercializing the substance in question.

The Agency would also like to make clearer the procedure a submitter intending to import the substance should use to allow a foreign manufacturer or supplier to provide confidential chemical identity information directly to EPA in order to complete a notice when the chemical identity is considered the proprietary information of the foreign party and cannot be disclosed to the submitter. As indicated by the proposed modification to § 720.25(b)(3), it is the importer's responsibility to make all of the contacts and arrangements with the foreign party for the timely transfer of this information to EPA in such a manner that EPA can easily link the information to the importer's notice.

The proposed amendments to § 720.25(b)(3) also indicate chemical identification requirements when submitters of substances to be manufactured or imported cannot possess full knowledge of the chemical identity of the substance to be reported because a purchased reactant or component used in the reported material has a confidential chemical identity that is the proprietary information of the supplier. Only in such a situation involving confidential trademarked or tradenamed reactants or starting materials, due to the complexity and logistical obstacles involved in generating correct CA identifications for substances based on multiple submissions from different sources, does the proposal allow the notice submitter to report directly to EPA all that is known about the substance identity. However, as previously discussed in Unit II of this preamble, the submitter must coordinate with the supplier to ensure that the remaining specific chemical identity information is sent by the supplier directly to EPA in a timely manner, in order to complete the notice and initiate review by EPA.

Further, EPA is proposing language in § 720.25(b)(9) to describe what constitutes an incomplete Bona Fide Notice, and how EPA would handle one. When an incomplete notice is received and identified as such, EPA will immediately return the notice directly to the submitter. The submitter would then have to resubmit the completed notice, in its entirety, in order to have EPA perform the Inventory search and respond to the notice.

3. *"Two percent rule" for polymers.* Under this proposal, the Agency would amend § 720.45(a) of the PMN rule and §§ 723.250(f)(2)(iv) and 723.250(o)(1) of the Polymer Exemption rule to allow a manufacturer the option of reporting monomers and other reactants on the basis of (a) the "amount charged" to the reaction vessel, which is the sole method currently allowed, or (b) the amount reacted and incorporated in the manufactured polymer. The proposed changes to § 723.250 are included in another action published elsewhere in this issue of the Federal Register. The current language in this regulation does not specify a basis for determining the percentage of monomer or reactant. However, as discussed earlier in this notice (Unit I.B.3 of this preamble), it has been EPA policy to require the percent (by weight) of a monomer or other reactant to be determined on the basis of the amount charged to the reactor, as a percentage of the dry weight of the manufactured polymer.

Concerning the use of the "incorporated" method, the percentage of chemical incorporation of a given reactant, and its "imputed charge" value, could possibly change if there was a modification in the manufacturing process, such as a change in reaction temperature or the method and/or order of charging reactants, etc. Such changes, which could be inadvertent as well as intentional, could possibly cause the weight percentage of a minor reactant to change from less than or equal to 2 percent to above 2 percent. If this reactant was not originally intended to be included in the polymer identity for TSCA purposes, the processing change could result in the isolation of a different, reportable polymer substance before a section 5 notice was submitted.

EPA emphasizes that a request to correct an initial Inventory reporting form (an Inventory correction request) or a section 5 notice (a PMN correction request) for which the review period has expired will not be accepted for the purpose of adding to the Inventory or to the Agency's PMN substance database, respectively, a new polymer identity that may occur if (1) a processing change causes the "imputed charge" value of a reactant to increase from less than or equal to 2 percent to above 2 percent, when reported percent composition data is based on amounts incorporated, or (2) the submitter changes from the "incorporation" to the "charged" computation method, or vice versa. If a different polymer is isolated under these circumstances that is not already in the Inventory, that polymer is subject to the PMN reporting requirements before it can be manufactured or imported for distribution in commerce.

4. *Multiple photocopies of section 5 submissions.* This proposed amendment to the PMN rule consists of a change in submission criteria at § 720.40(d)(2) that will require submitters to provide EPA

with one original and two copies of section 5 notices, in addition to a sanitized copy in which CBI has been deleted. Submitters would also be required to provide one original and two additional copies of any test data.

5. *Electronic transmission of section 5 notices.* This proposed amendment to the PMN rule at § 720.40(a) is designed to promote the use of electronic media for data submission. EPA is investigating the use of magnetic tape, floppy diskettes and electronic data interchange as means to submit information. In making this proposal, EPA is participating in a nation-wide trend toward reducing reliance on paper for information transfer. EPA has already taken steps in TSCA and other program areas to encourage electronic submission, and wishes to expand this effort to the PMN review program.

Information may be submitted electronically (on magnetic or other media) once EPA publishes a format for electronic submissions. Pilot projects using electronic submissions for the Inventory Update Rule and Toxic Release Inventory Rule will be used as a base line for enhancements to developing a standard Agency-wide format. Such submissions must meet this format and all other media specifications published by EPA. Persons submitting electronically must still complete and submit on paper the Certification and Submitter identification sections of EPA Form 7710–25; if attachments are submitted, the List of Attachments and all attachments must be submitted on paper.

6. *Mandatory form for Notice of Commencement (NOC).* Under the proposal, all PMN submitters would be required to use a standard one-page form to submit a NOC. In addition, the NOC information requirements at § 720.102(c), have been slightly expanded; however, all information can be provided on the one-page standard form.

The proposal would require every NOC received at EPA on or after the effective date of the final rule amendments to contain the required information on the new standard NOC reporting form. This form would automatically be provided to each PMN submitter as an attachment to EPA's acknowledgement of PMN receipt letter sent to submitters shortly after each PMN is received. Many submitters currently use a similar, voluntary form mailed to them, to report the required information.

The current NOC information reporting requirements include specific chemical identity, PMN number, the date when manufacture or import commences, and substantiation of CBI claims for chemical identity. This CBI substantiation is required by the time a NOC is submitted. Failure to provide written substantiation of a confidentiality claim for the chemical identity with the NOC, as required under 40 CFR 720.85, may result in a waiver of the confidentiality claim and disclosure of the chemical identity to the public.

Some additional information is required under the proposal to make it easier for EPA not only to process NOCs but to verify that submitters are reporting information in NOCs that is consistent with specific PMNs for the substances in question. EPA expects that this additional information would occasionally identify cases in which submitters mistakenly reported the wrong PMN case number in the NOC, or erroneously listed a substance identity that is very different from that which they intended to commence. In addition, the new requirements would enable submitters to provide certain updated information that may no longer be correct or appropriate as reported in the PMN.

In addition to the current NOC reporting requirements, EPA is proposing to amend NOC reporting to require that complete submitter identity information, including the name and address of the submitter, the name and dated signature of the authorized official, and the name and phone number of a technical contact in the United States, be provided on the form.

The amended NOC provisions would also now require a generic chemical name, which could either be the same generic name provided in the PMN, a generic name as revised by the submitter, as long as it masks no more of the chemical identity than the original generic name provided, or an improved or corrected generic name agreed to via negotiation with EPA.

Since one's intention to initially manufacture or import a substance sometimes changes between the time of PMN submission and NOC, the proposal requires submitters to specify in the NOC whether commencement occurred via manufacture or importation and the address of the site(s) under the control of the submitter at which manufacture commenced.

In addition to reasserting a CBI claim for chemical identity, the proposal requests a clear indication of whether the submitter identity is also claimed as confidential. Confidentiality claims can only be asserted by the submitter if the corresponding claims were made in the PMN.

All of the above proposed amendments to information requirements for NOCs involve information that the submitter already would know by the time manufacture or importation of the substance has commenced. Consequently, providing this information in the NOC would not constitute a significant reporting burden. EPA will consider an NOC incomplete if it is not submitted on the new form with all the required information.

III. Alternatives Considered

1. *Correct chemical identity*— a. *Alternative 1.* One alternative proposal being considered by EPA consists of requiring all submitters of section 5 notices and Bona Fide notices to obtain the correct chemical identity information directly from the Chemical Abstracts Service (CAS) using Method 1 as discussed in Unit II of this preamble.

EPA is considering this alternative proposal because the Agency believes that too much incorrect and incomplete chemical identity information may continue to be submitted in notices under the Agency's preferred proposal which allows a submitter to use other sources for chemical identity information (Method 1 or Method 2). The Agency believes that the level of EPA resource savings expected from mandatory use of the special extension of CAS Registry Services, which would require only minimal Agency screening and review of chemical identities in notices, cannot be achieved if submitters do not obtain substance identifications directly from CAS. Although EPA expects that most submitters will use CAS Registry Services for the reasons stated in Unit II of this preamble, the Agency realizes that in cases where submitters use alternative sources, EPA staff would have to invest significant resources to screen the quality of information. Further, the Agency would like to minimize the administrative burdens involved with notice suspensions, delays, submitter contact, and additional paperwork needed to properly amend notices that may be determined to be incomplete on the basis of incorrect chemical identity.

b. *Alternative 2.* This alternative is the same as EPA's preferred approach, allowing the use of Method 1 or Method 2 to obtain correct chemical identity information, except that submitters would have to obtain and report CASRNs for all substance identities that they do not claim as CBI, in addition to reporting CASRNs for all substances to which CASRNs have already been assigned.

Although having more substances reported with CASRNs under this alternative would save some EPA resources involved with chemical review and Inventory searching, the Agency recognizes that this approach could inadvertently discourage submitters from reporting substances without CBI claims for chemical identity as often as they should. Since EPA encourages and expects submitters to use CBI claims only when necessary, the Agency does not favor the use of this approach.

2. *"Two Percent Rule" for polymers—a. Alternative 1.* Retain the current "two percent rule" based on the weight of monomer or other reactants "charged" to the reactor.

EPA considered this alternative because it is much easier to calculate the weight of monomer or reactant "charged" to the reactor instead of analytically determining the actual composition of the polymer. The typical percentages of monomers or other reactants "as charged" could be directly calculated from batch records, and these calculations could be routinely made, if necessary, by people who do not have scientific training. The simplicity of this type of calculation also reduces the burden of chemical identity review for the Agency.

In addition, EPA and industry have been using this method of calculation and Inventory listing for 13 years. Consequently, Inventory consistency would be enhanced concerning what polymer listings actually represent.

This method also provides less chance of error, which would prevent significant increases in EPA's enforcement/compliance monitoring burden and liability to industry. By using the percent incorporated method, submitters could inadvertently fail to comply with section 5 of TSCA due to some processing change (other than the amounts of charged reactants) varying the incorporated percentages. For example, if the percent of a certain monomer incorporated in the polymer was determined to be just slightly under 2 percent, the monomer's percent incorporation could possibly increase above 2 percent due to some processing change, such as a modest variation in reaction temperature. If the submitter had reported that this monomer was not to be included in the chemical identity of the polymer, he/she would be in violation of the PMN Rule whenever the percent incorporation of that monomer exceeded 2 percent, if the new chemical identity including that monomer is not already in the Inventory. Such a technical violation of TSCA would not be easy to prevent or detect.

The Agency also believes that this method correlates reasonably well with the percent incorporation of most monomers.

However, the Agency is aware that the current method of reporting polymers provides industry with less flexibility and innovation capabilities since it may require PMN reporting for even minor changes in manufacturing processes. There may be relatively poor correlation between the percent charged versus incorporation, particularly for non-monomer reactants. Bases, acids, or other reactants are often charged at much more than stoichiometric amounts in order to achieve a certain pH, to drive the reaction to completion, or to generate more polymer chains with lower molecular weight, etc. Finally, EPA believed that it should take industry's request for revision of the "Two Percent Rule" under consideration, in line with the advances in analytical techniques for determining percent "incorporated", the desire to "harmonize" to the extent reasonable the Agency's polymer reporting requirements with other international reporting requirements, and the Agency's belief that allowing percent "incorporation" more accurately reflects the physical, chemical, and toxicological properties of polymers.

b. *Alternative 2.* Change to a 5 percent rule based on the amount charged.

EPA considered this option because it accommodates most typical use levels of reactants such as free radical initiators, chain transfer agents, salt forming reactants, etc. It would also allow industry more flexibility to modify existing polymers without submitting PMNs, thereby, significantly reducing EPA's reviewing burden. Historically, industry originally requested this level during the development of the Inventory reporting regulations.

EPA believes that this option would require that the Agency review the toxicological implications resulting from this alternative since the potential for chemically modifying polymer structures is increased somewhat when a monomer or reactant is increased from 2 to 5 percent, causing a larger potential variation in physical and chemical properties. Further, this method may allow monomers with reactant functional groups at levels that currently concern the Agency, e.g., cationic polymers. This method would not correlate chemical identity with percent incorporation as well as the EPA proposed amendment. Finally, this approach would not be consistent with the Agency's goal of harmonizing to the extent possible EPA's method of reporting polymers with other international reporting practices.

EPA requests comments on these alternatives, in particular, on the difficulty of obtaining accurate, reliable data using the percent "incorporated" method and the percentage of polymer submissions in which this method would be used.

IV. Economic Analysis

EPA has evaluated the potential costs of the proposed amendments for potential submitters of section 5 notices. The Agency's complete economic analysis is available in the public record for this rule (OPPTS–50593).

The regulatory impact analysis estimates the costs and benefits attributable to the proposed regulation. In this case, the analysis also contains estimates for the three additional proposed amendments to section 5 regulations that are published elsewhere in this **Federal Register**. These proposals would amend the Polymer Exemption Rule, the Low Volume Exemption Rule, and the Expedited Follow-up Rule. As these proposed regulations are amendments to current regulations, the costs and benefits are incremental, estimating the effect of the proposal with respect to the current regulation.

The costs and benefits associated with this proposed amendment are partially quantified; many of the benefits are unquantified but are considered to be of significant importance. Considering only the quantified costs and benefits, there is a slight cost increase for industry and a slight cost savings for government. Assuming either 1,000, 2,000, or 3,000 annual section 5 submissions, the savings as compared to the current regulation are estimated to be:

Annual Number of Submisssions	Annual Cost Savings ($ Million)	
	Industry	Government
1,000	(-0.1)	0.1
2,000	(-0.3)	0.2
3,000	(-0.4)	0.2–0.3

The aspects of the proposed amendment that have the greatest quantified cost impact on industry are the change in requirements for a bona fide TSCA Inventory search request and the requirement to provide correct chemical identification. Both requirements are expected to enable the Agency to more effectively utilize resources, thereby providing better service to industry. One of the major unquantified benefits of this proposal is the flexibility allowed industry by the changes to the "Two Percent Rule."

which allows industry to make minor compositional changes, providing more manufacturing control to the submitter and possibly reducing the number of section 5 submissions. Another unquantified change is the requirement to use a standardized form for notice of commencements (NOCs), the impact of which is expected to be minimal as most submitters are already using the form.

V. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPPTS-50593). The record includes basic information considered by the Agency in developing this proposed rule. EPA will supplement the record with additional information as it is received. A public version of the record without any confidential information is available in the TSCA Public Docket Office from 8 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Rm. NE-G004, 401 M St., SW., Washington, DC.

VI. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this rule would not be a "major" rule because it would not have an effect on the economy of $100 million or more, and it would not have a significant effect on competition, costs, or prices.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), EPA has determined that this rule would not have a significant impact on a substantial number of small businesses. EPA has not determined whether parties affected by this rule would likely be small businesses. However, EPA believes that the number of small businesses affected by this rule would not be substantial, even if all of the Polymer Exemption notice submitters were small firms.

C. Paperwork Reduction Act

The information collection requirements in this rule have been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3502 et. seq. and have been assigned OMB control number 2070-0012.

The public reporting burden for this collection of information is estimated to vary from 18 to 21 hours per response, with an average of 20 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M. St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 720

Chemicals, Environmental protection, Premanufacture notification, Hazardous materials, Recordkeeping and reporting requirements.

Dated: January 19, 1993.

William K. Reilly,

Administrator.

Therefore, 40 CFR chapter I, subchapter R, part 720 is proposed to be amended as follows:

PART 720 — [AMENDED]

1. The authority citation for part 720 would continue to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2613.

2. Section 720.25 is amended by revising paragraphs (a), (b)(1), (2)(i), (2)(iii), (2)(iv), (2)(v), (3), and by adding paragraphs (b)(2)(vi), (2)(vii), (2)(viii), and (b)(9) to read as follows:

§ 720.25 Determining whether a chemical substance is on the inventory.

(a) A new chemical substance is any chemical substance that is not currently listed on the TSCA Chemical Substance Inventory.

(b)(1) A chemical substance is listed in the publicly accessible inventory by a specific chemical name (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name) and a Chemical Abstracts Service (CAS) Registry Number if its identity is not confidential information. A confidential chemical substance, on the other hand, is listed in the public inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. The confidential substance is listed by its specific chemical name only in the confidential portion of the Inventory. A person who intends to manufacture or import a chemical substance not listed by specific chemical name in the publicly available inventory may ask EPA whether the substance is included in the confidential inventory. EPA will answer such an inquiry only if EPA determines that the person has a bona fide intent to manufacture or import the chemical substance for commercial purposes.

(2) * * *

(i) The specific chemical identity of the substance that the person intends to manufacture or import, using the most current, correct Chemical Abstracts (CA) name and the other correct chemical identity information stipulated in § 720.45(a).

* * * * *

(iii)(A) A brief description of the research and development activities conducted to date, including the year in which the person first started to conduct research or development activity on this substance, and the general types of research and development activities conducted thus far (e.g. synthesis, substance isolation/purification, formulating, product development, process development, end-use application, toxicity testing, etc.). The person must also indicate whether any pilot plant or production-scale plant evaluations have been conducted involving the manufacture or processing of this substance.

(B) If an importer is unable to provide the information requested in paragraph (b)(2)(iii)(A) of this section from the foreign manufacturer or supplier, the following information may be submitted:

(*1*) A brief statement indicating how long the substance has been in commercial use outside of the United States,

(*2*) The name of a country in which it has been commercially used,

(*3*) Whether or not the submitter believes that the substance has already been used commercially, in any country, for the same purpose or application that the submitter is intending.

(iv) A specific description of the major intended application or use of the substance.

(v) An infrared spectrum of the substance, or alternative spectra or other data which identifies the substance if infrared analysis is not suitable for the substance or does not yield a reasonable amount of structural information. When using alternative spectra or instrumental analysis, submit a spectrum or instrumental readout verifying use of that method.

(vi) The estimated date (month/year) in which the person intends to submit

a Premanufacture Notice (PMN) for this substance if EPA informs the notice submitter that the substance is not on the Inventory.

(vii) The address of the facility under the control of the submitter at which the manufacture or processing of the substance would most likely occur.

(viii)(A) For substances intended to be manufactured in the United States, a description of the most probable manufacturing process that would be used by the submitter to produce the substance for non-exempt commercial purposes.

(B) For substances intended to be imported, a brief description of how the submitter is most likely to process or use the substance for a commercial purpose. If the importer does not expect to process or use the substance at any facility under his control, a statement to this effect should be included along with a description of how the substance will be processed or used at sites controlled by others, if this information is known or reasonably ascertainable.

(3)(i) If an importer cannot provide all the information required by paragraph (b)(2) of this section because it is claimed confidential by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the required information directly to EPA and reference the importer's notice. If the appropriate supporting document from the foreign party is not received within 30 days after EPA receives the submitter's notice, the notice will be considered incomplete.

(ii) If a submitter cannot provide all of the required information as stipulated in § 720.45(a) because the new chemical substance is manufactured using a reactant that has a specific chemical identity claimed as confidential by its supplier, the notice must contain chemical identity information that is as complete as can be known by the submitter. In addition, a letter of support for the notice must then be sent to EPA by the chemical supplier of the confidential reactant, providing the specific chemical identity of this proprietary reactant. The letter of support must reference the submitter's notice, including the PMN User Fee Identification Number chosen by the submitter for this notice, if applicable. If the appropriate supporting document from the supplier is not received within 30 days after EPA receives the submitter's notice, the notice will be considered incomplete.

* * * * *

(9) If the required chemical identity information has not been reported correctly or completely in the notice (except as provided under paragraph (b)(3)(ii) of this section) or if any other required data or information has been omitted or is incomplete, EPA will consider the whole notice to be incomplete. As soon as an incomplete notice is identified as such by EPA, the Agency will immediately return the notice directly to the submitter. The submitter must then resubmit the whole, completed Bona Fide Notice to EPA in order to have the Agency perform the desired Inventory search and respond to the notice.

* * * * *

3. Section 720.40 is amended by revising paragraphs (a) and (d) to read as follows:

§ 720.40 General.

(a) *Use of the notice form; electronic submissions.* (1) Each person who is required by subpart B of this part to submit a notice must complete, sign, and submit a notice containing the information in the form and manner specified in this paragraph. The information submitted and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(2) Information may be submitted on paper, or electronically, as follows:

(i) Information submitted on paper must be submitted in the form and manner set forth in EPA Form No. 7710–25, which is available from the Environmental Assistance Division (TS–799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Information which is not submitted on a photocopy of the form (e.g., on a form created by commercial form-making software) must be in a format pre-approved by the Agency.

(ii) Information may be submitted electronically (on magnetic or other media) if and when EPA has published a format for electronic submissions. Such submissions must meet this format and all other media specifications published by EPA. Persons submitting electronically must still complete and submit on paper the Certification and Submitter Identification sections of Form 7710–25; if attachments are submitted, the List of Attachments and all attachments must be submitted on paper.

* * * * *

(d) *General notice requirements.* (1) Each person who submits a notice must provide the information described in § 720.45 and specified on the notice form, to the extent such information is known to or reasonably ascertainable by the submitter. In accordance with § 720.50, the notice must also include any test data in the submitter's possession or control, and descriptions of other data which are known to or reasonably ascertainable by the submitter and which concern the health and environmental effects of the new chemical substance.

(2) A person who submits a notice to EPA under this part must provide to EPA an original notice and two copies of the notice itself and two additional copies of all test data and any optional information attached to the notice form.

4. Section 720.45 is amended by revising paragraph (a) to read as follows:

§ 720.45 Information that must be included in the notice form.

* * * * *

(a)(1) The specific chemical identity of the substance that the person intends to manufacture or import, which includes the following:

(i) The currently correct Chemical Abstracts (CA) name for the substance, based on the 9th Collective Index (9CI) of CA nomenclature conventions, and consistent with listings for similar substances in the TSCA Chemical Substance Inventory (the Inventory). For each substance having a chemical composition that can be represented by a specific, complete chemical structure diagram (a Class 1 substance), a CA Index Name must be provided. For each chemical substance that cannot be fully represented by a complete, specific chemical structure diagram (a Class 2 substance), or if the substance is a polymer, a CA Index Name or CA Preferred Name must be provided (whichever is appropriate based on Chemical Abstracts Service (CAS) 9CI nomenclature rules and conventions),

(ii) The currently correct CAS Registry Number (CASRN) for the substance if a CASRN already exists for the substance in the CAS Registry File,

(iii) The correct molecular formula, for each Class 1 substance and any Class 2 substance for which a definite molecular formula is known or reasonably ascertainable,

(iv) A complete, correct chemical structure diagram for each Class 1 substance; a correct partial chemical structure diagram for a Class 2 substance or polymer, as complete as can be known, if one can be reasonably ascertained.

(2) For polymers, the submitter must also report the following:

(i) The specific chemical name and CAS Registry Number (if available) of each monomer and other reactant used, at any weight percent, to manufacture the polymer. Tradenames or generic

names of chemical reactants or monomers are not acceptable as substitutes for specific chemical names.

(ii) The typical percent of each monomer and other reactant in the polymer (by weight percent of total polymer), and the maximum residual amount of each monomer present in the polymer.

(iii) The reactants used at 2 weight percent or less (based on the dry weight of the polymer manufactured) that should be included as part of the polymer description on the Inventory, where the weight percent is based on either (A) the weight of reactant charged to the reaction vessel, or (B) the weight of chemically combined (incorporated) reactant in the polymer.

(iv) The submitter must specify which method of computation is used; that is, whether the calculation is based on the weight of reactants "as charged" or "as incorporated." If the submitter specifies on the basis of incorporated weights of reactants in the polymer, analytical data to support this determination must be maintained at the site of manufacture. The "percent (by weight)" of a monomer or other reactant is the weight of the reactant expressed as a percentage of the weight of the polymeric chemical substance manufactured. If the submitter uses the "as charged" method of computation, the weight of a reactant consists of its full amount charged to the reaction vessel. If the optional "incorporated" method of reporting is used, the weight of a reactant is the minimum weight of that reactant required by theory to account for the actual weight of reactant or reactant unit chemically incorporated into the polymeric substance manufactured.

(v) Measured or estimated values of the minimum number-average molecular weight of the polymer and the amount of low molecular weight species below 500 and below 1,000 molecular weight, with a description of how the measured or estimated values were obtained.

(3) Submitters must use one of the following two methods to develop or obtain the specified chemical identity information and identify the method used in the notice:

(i) *Method 1.* Using this method, the submitter would obtain the correct chemical identity information required by § 720.45(a)(1) directly from CAS prior to submitting a notice to EPA.

(ii) *Method 2.* A submitter using this method can obtain the correct chemical identity information required by § 720.45(a)(1) from any source, as long as the information is consistent with Inventory listings for similar substances. This section of the notice will be incomplete according to § 720.65(c)(1)(vi) if the submitter uses Method 2 and any chemical identity information is considered incorrect by EPA.

(4) If an importer submitting the notice cannot provide all the information stipulated at § 720.45(a) because it is claimed as confidential by the foreign manufacturer or supplier of the substance, the importer must have the foreign supplier follow the procedures at § 720.45(a)(3) and provide the correct chemical identity information stipulated in § 720.45(a) directly to EPA in a joint submission or as a letter of support to the notice, which clearly references the importer's notice and PMN User Fee Identification Number. The statutory review process will start upon receipt of complete, correct information from the foreign party.

(5) If a manufacturer cannot provide all the information stipulated in § 720.45(a) because the new chemical substance is manufactured using a reactant having a specific chemical identity claimed as confidential by its supplier, the manufacturer must submit a notice directly to EPA containing all the information known by the manufacturer about the chemical identity. In addition, the supplier of any confidential reactant must submit a letter of support directly to EPA providing the specific chemical identity of the confidential reactant. The letter of support must reference the notice submitter's name and PMN User Fee Identification Number. The statutory review period will commence upon receipt of both the notice and letter of support.

5. Section 720.80 is amended by revising paragraph (b)(2) to read as follows:

§ 720.80 General provisions.

* * * * *

(b) * * *

(2) If any information is claimed as confidential, the person must submit two copies of each notice form (or electronic submission) and any attachments.

(i) One copy of the form (or electronic submission) and attachments must be complete. In that copy, the submitter must designate that information which is claimed as confidential in the manner prescribed on the notice form (or in EPA's electronic submission instructions).

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file. Once this copy has been in the public file for more than 30 days, any information contained within the copy will be presumed to be in the public domain.

(iii) If the submitter does not provide the second copy, or information in a health and safety study (except data claimed as confidential in accordance with § 720.90(b)) is deleted from the second copy, the submission will be deemed incomplete and the notice review period will not begin until EPA receives the second copy or the health and safety study information is included, in accordance with § 720.65(c)(1)(vi).

* * * * *

6. Section 720.102 is amended by revising paragraphs (c) to read as follows:

§ 720.102 Notice of commencement of manufacture or import.

* * * * *

(c) *Information to be reported on form.* (1) The notice must be submitted on EPA (Form 7710——) (Form number to be assigned), which is available from the Environmental Assistance Division (TS–799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The form must be signed and dated by the submitting person or authorized official. All information specified on the form must be provided. The notice must contain the following information:

(i) The specific chemical identity.

(ii) A generic chemical name (if the chemical identity is claimed as confidential by the submitter).

(iii) The premanufacture notice (PMN) number.

(iv) The date when the submitter commenced manufacture or import for a commercial purpose (indicating whether the substance was initially manufactured in the United States or imported).

(v) The name and address of the submitter.

(vi) The name of the authorized official.

(vii) The name and phone number of a technical contact in the United States.

(viii) The address of the site(s) under the control of the submitter where commencement of manufacture occurred.

(ix) Clear indications of whether or not the chemical identity and/or the name of the submitter is presently claimed as confidential by the submitter.

(2) If the submitter claims the chemical identity confidential, and wants the identity to be listed on the confidential Inventory, the claim must

be reasserted and substantiated in accordance with § 720.85(b). Otherwise, EPA will list the specific chemical identity on the public Inventory. Submitters who did not claim the chemical identity or submitter identity to be confidential in the PMN cannot claim either of these identities as confidential in the Notice of Commencement.

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